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10/764,674	01/23/2004	David G. Quinn	5935/83	9464

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	10764674	QUINN, DAVID G.
	Examiner	Art Unit
	Emily Schmidt	3767

SEARCHED

Class	Subclass	Date	Examiner
604,	43, 101.01-101.04, 103.04, 158, 164.01, 164.09-165.02, 170.02, 172, 264, 270,284, 516, 523-529, 533, 535, 538, 539 (updated)	2/24/2009	ES

SEARCH NOTES

Search Notes	Date	Examiner
East-inventor, assignne, text, citation (updated)	2/24/2009	ES
Searched Plus search	8/21/2007	EW
Palm inventor search (updated)	2/24/2009	EWS
Received Search suggestions from Examiner Andrew Gilbert	9/5/2007	EW

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

DETAILED ACTION

Priority

1. This application claims priority to Application No. 60/351,698 filed on January 24, 2002 and Application PCT/US03/02347 filed on January 24, 2003, the instant Application appears to add new matter not presented in the prior applications. Specifically, regarding at least the flexible plastic enteral feeding catheter tube. Therefore, the filing date of January 23, 2004 is being accorded to the claims.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not appear to specifically disclose flexible wire stylets or a flexible plastic enteral feeding catheter tube.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 7-14 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Application as filed does not appear to disclose that the enteral feeding catheter tubes are plastic.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 7-8 and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Burney et al. (US 4,986,814).

With regard to claim 7, Burney et al. teach a catheter and stylet assembly, comprising: a) a catheter tube sub-assembly including a flexible plastic enteral feeding catheter tube having a distal end and a proximal end, said tube having a connector on its proximal end (Fig. 1 catheter 22 with connector 34 is capable of being for enteral feeding, Col. 2 line 24); and b) a first stylet sub-assembly including a primary flexible wire stylet having distal and proximal ends, said first stylet sub-assembly also including a first stylet fitting in which the proximal end of said primary stylet is seated (Fig. 1 cannula 24 is functionally equivalent to a stylet and is flexible it is thin walled and made of stainless steel, Col. 2 lines 44-46, having fitting 44); and c) a second stylet sub-assembly including a secondary flexible wire stylet having distal and proximal ends, said secondary stylet sub-assembly also including a second stylet fitting in which the proximal end of said secondary stylet is seated (Fig. 1 stylet 26, again effectively stainless steel wire, fitting 50, Col. 2 line 47); d) said first stylet fitting being releasably seated in said connector with said primary stylet extending into said tube and said secondary stylet fitting being releasably connected to said first stylet fitting with said secondary stylet extending into said first stylet fitting and said tube (When assembled all three locking members are releasably seated

in/connected to each other. The fitting of the cannula (Fig. 1 element 44) is seated in the fitting of the catheter (Fig. 1 element 34). The stylet fitting (Fig. 1 element 50) is connected to the fitting of the cannula (Fig. 1 element 44, Fig. 2, Col. 2 lines 40-43, 49-52)).

With regard to claim 8, in Fig. 1 of Burney et al. element 50 is taken to be the sleeve fitting for the secondary stylet which releasably connects the first stylet fitting to the second stylet fitting.

With regard to claim 30, Burney et al. teach an enteral feeding catheter and stylet assembly for naso-gastric insertion of the catheter into a patient; comprising: a) a catheter tube sub-assembly including a flexible plastic enteral feeding catheter tube having a distal end and a proximal end, said tube having a feeding connector on its proximal end (Fig. 1 catheter 22 with connector 34 is capable of being for enteral feeding, Col. 2 line 24); b) a first stylet sub-assembly including a primary flexible wire stylet having distal and proximal ends, said first stylet sub-assembly also including a first stylet fitting in which the proximal end of said primary stylet is seated (Fig. 1 cannula 24 is functionally equivalent to a stylet and is flexible it is thin walled and made of stainless steel, Col. 2 lines 44-46, having fitting 44); and c) a second flexible wire stylet sub-assembly including a secondary stylet having distal and proximal ends, said secondary stylet sub-assembly also including a second stylet fitting in which the proximal end of said secondary stylet is seated Fig. 1 stylet 26, again effectively stainless steel wire, fitting 50, Col. 2 line 47); d) said first stylet fitting being seated in said connector with said primary stylet extending into said tube and said secondary stylet fitting being connected to said first stylet fitting with said secondary stylet extending into said tube through said first stylet fitting (When assembled all three locking members are releasably seated in/connected to each other. The fitting of the

cannula (Fig. 1 element 44) is seated in the fitting of the catheter (Fig. 1 element 34). The stylet fitting (Fig. 1 element 50) is connected to the fitting of the cannula (Fig. 1 element 44, Fig. 2, Col. 2 lines 40-43, 49-52)).

With regard to claim 31, in Fig. 1 of Burney et al. element 50 is taken to be the sleeve fitting for the secondary stylet which connects the first stylet fitting to the second stylet fitting and through which the second stylet extends.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 9 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (U.S. Patent 4,986,814) as applied to claims 7 and 31 above, and further in view of Mar (U.S. Patent 4,771,778).

With regard to claims 9 and 32, Burney et al. teach a catheter and stylet assembly substantially as claimed. Burney et al. does not teach a visible mark on a stylet located 12 inches from its stylet connector. Mar teaches a marker on a core wire, taken to be functionally equivalent to a stylet, disposed in a catheter (Fig. 2 elements 31 and 46). It would have been obvious to one of ordinary skill in the art at the time the invention was made to place a marker on the stylet in Burney et al. because Mar teaches that marks may be placed on the wire disposed in the catheter. It is advantageous because it is a radiopaque marker that can be viewed using fluoroscopy and aids in observing the position the body (Col. 2 lines 59-60, Col. 4 lines 1-2). It

would be a matter of obvious design choice for the location of the mark. The mark will be located as desired by the user depending on how they are going to use viewing the mark via fluoroscopy. Ultimately, the mark is still being used to aid the user in knowing the location, within the patient, of the item it is placed on. For this reason, positioning a mark approximately 12" from its stylet connector would have been an obvious expediency in the art.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (U.S. Patent 4,986,814) as applied to claim 7 above, and further in view of Abrahmson et al. (U.S. Patent 5,382,238).

With regard to claim 10, Burney et al. teach a catheter and stylet assembly substantially as claimed. Burney et al. does not teach a catheter with two lumens. However, Abrahamson teaches a catheter tube with two lumens (Col. 3 line 12). This allows a stiffener to be inserted in one lumen leaving the other lumen free for fluid delivery. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a double lumen catheter in the device of Burney et al. because Abrahmson et al. teaches using a double lumen catheter and further to insert the stylets into only one of the lumens because this allows a wire stiffener to be inserted and then the catheter can be used in a conventional manner employing two lumens (Col. 4 paragraph 2), stiffening and fluid delivery can occur simultaneously. The catheter is capable for use in enteral feeding.

10. Claims 11 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (U.S. Patent 4,986,814) as applied to claims 7 and 31 above, and further in view of further in view of Quinn (U.S. Patent 5,810,787).

With regard to claims 11 and 33, Burney et al. teach a catheter and stylet assembly substantially as claimed. Burney et al. does not teach a size 8 Fr single lumen catheter with a bullet nose bolus on its distal end. However, Quinn teaches a bolus with a bullet tip section located on the distal end of an 8 Fr tube (Fig. 1, Col. 3 lines 57 and 65). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a catheter consisting of an 8 Fr tube with a bullet nose bolus on the distal end in Burney et al. because it is directly taught by Quinn to apply equally well to all types of catheters (Col. 3 lines 18-22). The catheter is capable for use in enteral feeding.

11. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (U.S. Patent 4,986,814) and Quinn (U.S. Patent 5,810,787)as applied to claim 11 above, and further in view of Frassica (U.S. 6,379,334) and Meng et al (U.S. Patent 6,506,181 B2).

With regard to claim 34, Burney et al. teach a catheter and stylet assembly substantially as claimed. Burney et al. does not teach a catheter coated with a lubricant. Frassica teaches a water soluble lubricant being disposed on the distal tip of a catheter (Col. 17 lines 20, 23-24). Meng et al. teaches that a lubricious material may be disposed on the cavity of a catheter (abstract), putting it on the cavity of the catheter means it is disposed inside the catheter. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply a lubricant inside and outside the catheter adjacent to the bolus in the device of

Burney et al. in view of Quinn because Frassica teaches lubricating the distal tip of the catheter, also embodying the outside, this is where the bolus in the application is located, and Meng et al. teaches coating the inside surface of a catheter. There is incentive for lubricating the outside distal area of the catheter to make it more easily maneuvered inside the patient and inside the catheter tube so that the instruments moving inside the catheter, the stylets, move easily.

12. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn (US 2001/0018576 A1) in view of Andersen et al. (US 4,594,074), and Burney et al. (U.S. Patent 4,986,814).

With regard to claim 12, Quinn et al. teach a catheter and stylet assembly, comprising: a catheter tube assembly including a unitary flexible plastic enteral feeding catheter tube ([0135]) containing two lumens and a smaller diameter unitary flexible plastic enteral feeding catheter tube containing a single lumen; b) said 8 Fr tube and said smaller diameter tube being connected by a unitary bolus formed independently of said 8 Fr tube and said smaller diameter tube having a side port; c) said enteral feeding catheter tube having a proximal and a distal end, said proximal end having a connector on its proximal end (Fig. 27); and d) said smaller diameter enteral feeding catheter tube containing a single lumen formed separately from said two lumen tube (regarding elements a-d see Reference Figure 1 below, the double lumen portion is formed separately of the bolus and single lumen portion as evidenced by the cross-hatching further generally see Fig. 29). The device is capable for use with enteral feeding.

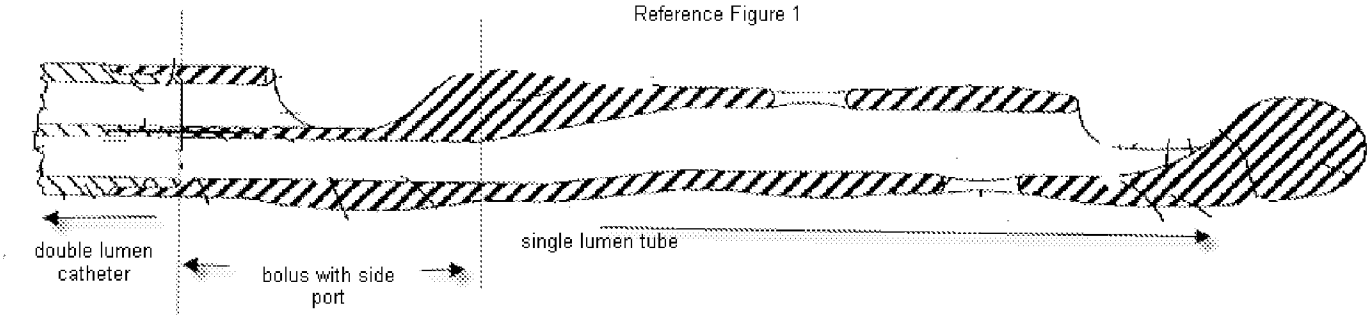
Quinn does not teach using an 8 Fr tube. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made use an 8 Fr tube

because Applicant has not disclosed that such a size provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the tube of Quinn because it still allows for adequate fluid delivery.

Quinn teaches the dual lumen tube to be formed separately of the bolus and single lumen tube. Quinn does not teach the bolus to be formed independently of both the double and single lumen tubes. However, Andersen et al. teach a catheter assembly for enteral feeding which uses an intermediate bolus to connect two tubes, the portions of the device are constructed independently of one another (Fig. 7). This would allow for the device to be constructed with varying materials and flexibility depending on where the device will be used. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to for the bolus independently of the tubes in the device of Quinn because Andersen et al. teaches such construction is beneficial and art recognized for use in enteral feeding and would allow for the device to be constructed with varying materials and flexibility depending on where the device will be used. Further, it would have been obvious to a person of ordinary skill in the art at the time the invention was made construct the pieces separately since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin V. Erlicnman*, 168 USPQ 177, 179.

Quinn does not teach first and second stylet subassemblies. However, Burney et al. teach a catheter with a first stylet sub-assembly including a primary stylet having distal and proximal ends, said first stylet sub-assembly also including a first stylet fitting in which the proximal end of said primary stylet is seated (Fig. 1 cannula 24 is functionally equivalent to a stylet, Col. 2

lines 44-46, having fitting 44); a second stylet sub-assembly including a secondary stylet having distal and proximal ends, said secondary stylet sub-assembly also including a second stylet fitting in which the proximal end of said secondary stylet is seated (Fig. 1 stylet 26 fitting 50, Col. 2 line 47); said first stylet fitting being releasably seated in said connector with said primary stylet extending into said two lumen tube and said secondary stylet fitting being connected to said first stylet fitting with said secondary stylet extending into said tube through said first stylet fitting (When assembled all three locking members are releasably seated in/connected to each other. The fitting of the cannula (Fig. 1 element 44) is seated in the fitting of the catheter (Fig. 1 element 34). The stylet fitting (Fig. 1 element 50) is connected to the fitting of the cannula (Fig. 1 element 44, Fig. 2, Col. 2 lines 40-43, 49-52)). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a stylet configuration as taught in Burney et al. in the device of Quinn because it would allow the user to appropriately control and guide the catheter.



With regard to claim 13, Quinn teaches a catheter and stylet assembly substantially as claimed. Quinn does not specifically disclose the catheter tube being a 5 or 6 Fr size tube. It

would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made use a 5 or 6 Fr tube because Applicant has not disclosed that such a size provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the tube of Quinn because it still allows for adequate fluid delivery.

13. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn (US 2001/0018576 A1), Andersen et al. (US 4,594,074), and Burney et al. (U.S. Patent 4,986,814). as applied to claim 12 above, and further in view of Frassica (U.S. 6,379,334) and Meng et al (U.S. Patent 6,506,181 B2).

With regard to claim 14, Quinn teaches a catheter and stylet assembly substantially as claimed. Burney et al. does not teach a catheter coated with a lubricant. Frassica teaches a water soluble lubricant being disposed on the distal tip of a catheter (Col. 17 lines 20, 23-24). Meng et al. teaches that a lubricious material may be disposed on the cavity of a catheter (abstract), putting it on the cavity of the catheter means it is disposed inside the catheter. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply a lubricant inside and outside the catheter adjacent to the bolus in the device of Quinn because Frassica teaches lubricating the distal tip of the catheter, also embodying the outside, this is where the bolus in the application is located, and Meng et al. teaches coating the inside surface of a catheter. There is incentive for lubricating the outside distal area of the catheter to make it more easily maneuvered inside the patient and inside the catheter tube so that the instruments moving inside the catheter, the stylets, move easily.

Response to Amendment

14. The amendments to the claims and specification have been entered and overcome the previous objections to the specification and rejections under 112.

Response to Arguments

9. Applicant's arguments filed December 3, 2008 have been fully considered but they are not persuasive. Applicant has argued that Burney et al. does not teach flexible wire stylets, the Examiner respectfully disagrees. The identified stylets are made of flexible materials and effectively constitute wires. No special definition has been provided for the term wire which would preclude it from including a hollow member. The newly added amendments to claim 12 are addressed in the new rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Schmidt whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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